

MEETING SUMMARY
EXECUTIVE COMMITTEE CONFERENCE CALL

Convened in Ariel Rios North Building Rm 5530
1200 Pennsylvania Ave. Washington, DC
September 22, 2000 11:00 am EDT

ACTIONS

ACTION 1: The Executive Committee approved the Environmental Health Committee's *"Review of the Agency's Draft Report to the Congress: 'Characterization of Data Uncertainty and Variability in IRIS Assessments, Pre-Pilot vs. Pilot/post-Pilot'"* subject to edits referenced in the meeting. Dr. Greer abstained.

ACTION 2: The Executive Committee approved the Drinking Water Committee's *"Report on Certain Elements of the Proposed Arsenic Drinking Water Regulation"*, subject to final approval by the two Discussants (Drs. Lippmann and Seeker) and Dr. Greer, acting as authorized vettors on behalf of the EC.

ACTION 3: The Executive Committee approved the Integrated Human Exposure Committee's *Review of the Draft Strategy for the Analysis of NHEXAS Data"*, subject to final edits referenced in the meeting.

ACTION 4: The Executive Committee approved the Drinking Water Committee's *"Advisory on EPA's Draft Contaminant Candidate List (CCL) Research Plan"*, subject to final edits discussed at the meeting.

INSTRUCTIONS

INSTRUCTION 1: Dr. Lippmann asked Dr. Greer to transmit the comments of Dr. Allen Smith on the DWC report to Dr. Barnes for distribution to the entire EC.

INSTRUCTION 2: EC members should email to Dr. Barnes within two weeks their suggestions of actual SAB experience that both demonstrate the problem (i.e., formulation of a charge resulting in a request for information or an assignment of a task to the Agency of the SAB that could not plausibly be accomplished on the basis of existing information) and positive examples (i.e., instances of especially well-formulated charges to the Agency of the SAB, or cases in which advance dialogue avoided what might have otherwise been an implausible charge.

INSTRUCTION 3: Dr. Barnes will have Dr. Nugent set up a conference call with Drs. Morgan, Bull, and Young to discussed the up-coming workshop session on science and stakeholders.

INSTRUCTION 4: Dr. Fowle will work with Drs. Schnoor and Seeker on the feasibility and advisability of having a joint Consultation with SAB and BOSC on ORD's new strategic plan.

INSTRUCTION 5: The EC instructed SAB Staff to distribute the SAB policy on the respective roles of Members and Consultants to all SAB Members and Consultants by Monday, Sept. 25.

MEETING SUMMARY
EXECUTIVE COMMITTEE CONFERENCE CALL

Convened in Ariel Rios North Building Rm 6013

1200 Pennsylvania Ave. Washington, DC

September 22, 2000 11:00 am EDT

1. Attendees

EC Members present on the telephone:

Dr. Morton Lippmann, Chair

Dr. Henry Anderson

Dr. Richard Bull

Dr. Linda Greer

Dr. Joe Mauderly

Dr. Granger Morgan

Dr. W. Randall Seeker

Dr. Mark Utell

Other SAB Members

Dr. Rhodes Trussell, DWC

Other SAB Panelists

Dr. John Rosen, DWC Arsenic Panel

Liaison participants

Dr. Jerry Schnoor, Liaison from ORD Board of Scientific Counselors (BOSC)

Designated Federal Officer, present in AR 5530: Dr. Donald Barnes

Others present in AR 5530

Dr. Jack Fowle, Deputy SAB Staff Director

Mr. Thomas Miller, DWC DFO

Mr. David Goldstein, General Accounting Office

There were an estimated eight members of the public who joined at some time during the call but did not identify themselves.

2. Agenda

The meeting followed the agenda (Attachment A)

3. Comment from the Chair

Dr. Lippmann announced that he would not be present at the Executive Committee (EC) meeting on Nov. 1-2, since he will be chairing the SAB Dioxin Panel that meets at the same time. Dr. Barnes will work with the Administrator's Office to ensure that a suitable substitute is present to Chair the EC meeting.

4. Consideration of the Environmental Health Committee's "Review of the Agency's Draft Report to the Congress: 'Characterization of DATA Uncertainty and Variability in IRIS Assessments, Pre-Pilot vs. Pilot/post-Pilot'" (Attachment B)

EHC Chair, Dr. Utell, introduced the work of the Committee.

Lead Discussant, Dr. Lippmann, had provided written comments to the DFO (Attachment C). His comments were primarily editorial in nature.

Associate Discussant, Dr. Greer, had not had time to read the draft report. She requested that her abstention be noted.

Associate Discussant, Dr. Bull, disclosed that in recent weeks he has become a subcontractor that was doing work for the Agency on the Integrated Risk Information System (IRIS). He concurred with Dr. Lippmann's comments and offered some editorial comments (Attachment D)

Dr. Morgan indicated that he had not received a copy of the report. All of the others members indicated that they had.

ACTION 1: The Executive Committee approved the Environmental Health Committee's *"Review of the Agency's Draft Report to the Congress: 'Characterization of DATA Uncertainty and Variability in IRIS Assessments, Pre-Pilot vs. Pilot/post-Pilot'"* subject to edits referenced in the meeting. Dr. Greer abstained.

4. Consideration of the Drinking Water Committee's "Report on Certain Elements of the Proposed Arsenic Drinking Water Regulation" (Attachment E)

DWC Chair, Dr. Bull, introduced the report. He noted that there was no consensus on some points, as illustrated by a Minority Report, authored by one of the Consultants and ascribed to by one of the Members. He referred to comments recently received from the Agency (Attachment F) that raised concern that the DWC had gone beyond its charge and may have misunderstood some of the issues associated with practical quantitation limit (PQL). He planned to resolve the technical aspect of the matter of the PQL, eliminating the section if that was appropriate. The EC noted that the Charge to the SAB -- a product of negotiation between the Board and the Agency -- is designed to guide the review, not to constrain it; hence, the EC was comfortable with the scope of the DWC's work.

Lead Discussant, Dr. Seeker, augmented his written comments (Attachment G) with complementary remarks about the report. In his view, the Minority Report was an appropriate way to handle and issue about which there were at least two points of view. Dr. Bull responded to the four issues raised in Dr. Seeker's comments:

- a. Issue 1: The DWC case regarding PQL should be made more firmly. Response: As noted above, Dr. Bull will be addressing that matter.
- b. Issue 2: Is it normal practice for there to be a risk assessment associated with a drinking water regulation? Response: Yes.
- c. Issue 3: Some of the comments about handling of treatment wastes on p. 28 is unclear. Response: Dr. Bull will clarify those points.

- d. Issue 4: A "phased approach" -- in terms of increasingly tighter controls over time -- is difficult to do. Response: The DWC's intention was to suggest gradually increasing over time the number of systems subject to the regulation and applying "lessons learned" from the earliest implementations in an adaptive manner.

Associate Discussant, Dr. Lippmann, summarized his written comments (Attachment H) in which he complimented the DWC on their work and recommended approval of their report.

Dr. Greer expressed significant concerns about three aspects of the report:

- a. The DWC appears to disparage the recent report of the National Research Council (NRC) on arsenic. In support of this position, she reference comments from Dr. Allen Smith, an member of the NRC Panel, that allegedly take issue with the DWC's treatment of the NRC report. None of the member of DWC or the EC were aware of Dr. Smith's comments.

INSTRUCTION 1: Dr. Lippmann asked Dr. Greer to transmit the comments of Dr. Allen Smith on the DWC report to Dr. Barnes for distribution to the entire EC.

- b. Given the necessarily wide range of experts on the DWC, it was inappropriate for all of them to weigh in on issues of public health.
- c. The format of the report has the effect of relegating the Minority Report to ancillary status.

Dr. Bull did not agree that the DWC report disparages the NRC report in any way. The presence of an NRC Panel member on the DWC Panel (Dr. Louise Ryan) was, in part, designed to avoid such a situation, however unintended it might be. He felt that the two reports are in substantial agreement regarding the need to reduce the current regulatory level, the need for a risk assessment to guide such a decision, and the position that establishing a particular level is a policy call to which scientific facts can contribute but not dictate. In his view the DWC supports the NRC conclusions, while citing additional pertinent studies that have been published since release of the NRC report that basically reinforce its message. In particular, the Taiwan study is the best study available upon which to base regulation, but it has several important shortcomings that need to be explicitly addressed in a needed risk assessment. The DWC intended to acknowledge that there are US populations with dietary deficiencies, but that these deficiencies do not include selenium deficiency, which is a demonstrated factor in arsenic toxicity.

Dr. Rosen joined to conversation to say that his Minority Report raised a series of concerns about the issues discussed and the process by which they were discussed. His concern is not that the Minority Report "stands alone"; in fact, he believes that it more sharply presents his points that way. Rather, he is concerned that the Minority is inappropriately referred to in the body of the report. Dr. Bull indicated that he would include those additional references.

In addition, Dr. Rosen expressed concern for children who might be at risk and would remain so during a "phased approach". Dr. Bull indicated that the comment about a "phased approach" is a policy suggestion, not a scientific conclusion and will be so labeled in the report.

Dr. Rosen and Dr. Bull briefly exchanged their views about the range of expertise represented on the Panel to discuss health-related issues, such as issuance of a health advisory.

Dr. Morgan said that he felt that all of the concerns he heard expressed could be handled by an appropriately editing of the report. Dr. Anderson expressed an interest in looking at the report and comments in greater detail. He was sympathetic to some of the points raised, but felt that the Minority Report was more effective as a separate, unintegrated piece.

ACTION 2: The Executive Committee approved the Drinking Water Committee's *"Report on Certain Elements of the Proposed Arsenic Drinking Water Regulation"*, subject to final approval by the two Discussants (Drs. Lippmann and Seeker) and Dr. Greer, acting as authorized vettors on behalf of the EC.

5. Consideration of the Integrated Human Exposure Committee's *Review of the Draft Strategy for the Analysis of NHEXAS Data*" (Attachment I)

Dr. Anderson, IHEC Chair, introduced the report.

Lead Discussant, Dr. Mauderly, referred to his written comments (Attachment J) that were largely editorial. He noted that many of his suggestions had been incorporated into a re-draft of the report. He pursued three issues:

- a. The use of iconographics instead of hard numbers.
- b. The meaning of "reconciling" the results of the work of the three consortia.
- c. The reference to dose-response information in what is essentially an exposure assessment exercise.

Dr. Anderson will provide clarifying language, including the use of order of magnitude estimates to address the first issue.

Associate Discussant, Dr. Bull, saw no major problems. He identified a need in the report for additional information about the context of the study. Dr. Anderson indicated that that matter has now been addressed editorially.

ACTION 3: The Executive Committee approved the Integrated Human Exposure Committee's *Review of the Draft Strategy for the Analysis of NHEXAS Data*", subject to final edits discussed at the meeting.

6. Consideration of the Drinking Water Committee's *"Advisory on EPA's Draft Contaminant Candidate List (CCL) Research Plan"* (Attachment K)

Dr. Bull introduced the advisory, noting that a principal comment was that the "plan" was not a plan; it was more a "strategy"..

Lead Discussant, Dr. Morgan, amplified on his written comments (Attachment L), concluding that the advisory should be approved and sent to the Administrator.

Associated Discussant, Dr. Johnson, was unable to participate in the call, but she had provided written comments (Attachment M) that suggested modest changes.

ACTION 4: The Executive Committee approved the Drinking Water Committee's *"Advisory on EPA's Draft Contaminant Candidate List (CCL) Research Plan"*, subject to final edits discussed at the meeting.

7. Other issues

a. Improving the Science-Policy Interface

Dr. Mauderly had e-mailed EC members his analysis (Attachment N) of the issue concerning "Improving the Science-Policy Interface". He included suggestions for next steps.

INSTRUCTION 2: EC members should email to Dr. Barnes within two weeks their suggestions of actual SAB experience that both demonstrate the problem (i.e., formulation of a charge resulting in a request for information or an assignment of a task to the Agency of the SAB that could not plausibly be accomplished on the basis of existing information) and positive examples (i.e., instances of especially well-formulated charges to the Agency of the SAB, or cases in which advance dialogue avoided what might have otherwise been an implausible charge.

b. EC Workshop on Science and Stakeholders

The final workshop in the series will be conducted by Dr. Morgan on the afternoon of November 1.

INSTRUCTION 3: Dr. Barnes will have Dr. Nugent set up a conference call with Drs. Morgan, Bull, and Young to discussed the up-coming workshop session on science and stakeholders.

c. ORD Strategic Plan and the SAB and BOSC

Dr. Schnoor, BOSC Chair, reported that BOSC had been asked to participate in a Consultation with ORD regarding the updated ORD Strategic Plan. Dr. Fowle noted that the Research Strategies Advisory Committee (RSAC) had received a similar request. While Consultations are encounters with the Agency at which individuals, not committees or organization, provide comments and insights verbally (not in writing) to the Agency, the EC felt that there might be benefit from having a joint BOSC/SAB Consultation on this matter.

INSTRUCTION 4: Dr. Fowle will work with Drs. Schnoor and Seeker on the feasibility and advisability of having a joint Consultation with SAB and BOSC on ORD's new strategic plan.

d. Policy on roles of Members and Consultants

Dr. Mauderly noted that the EC had approved the policy on the relative roles of Members and Consultants at the July EC meeting and had instructed that Staff distribute the policy to all SAB Members and Consultants. Dr. Barnes reported that he had

- 1) Asked the Office of the General Counsel (OGC) to review the document to ensure that the policy was not in conflict with any existing policies or laws.
- 2) Worked with officials in the Office of Air and Radiation (OAR) to ensure that the language in the policy appropriately addressed the issue that engendered their concern on this topic in the first place.

Both parties have agreed to the policy with minor edits and clarifications

INSTRUCTION 5: The EC instructed SAB Staff to distribute the SAB policy on the respective roles of Members and Consultants to all SAB Members and Consultants by Monday, Sept. 25.

e. SAB to testify before Subcommittee of the House Science Committee

Dr. Lippmann announced that he and Dr. Hopke are scheduled to testify before the Senate Committee on Environment and Public works on Oct. 3.

Respectfully submitted,

Concurred,

/s/

/s/

Donald G. Barnes, DFO

Morton Lippmann PhD
Interim SAB Chair

ATTACHMENTS

Attachment a -- Agenda

Attachment B -- EHC's draft *"Review of the Agency's Draft Report to the Congress:
'Characterization of DATA Uncertainty and Variability in IRIS
Assessments, Pre-Pilot vs. Pilot/post-Pilot'"*

Attachment C -- Dr. Lippmann's comments on the draft

Attachment D -- Dr. Bull's comments on the draft

Attachment E -- DWC's draft *"Report on Certain Elements of the Proposed Arsenic Drinking
Water Regulation"*

Attachment F -- The Agency comments on the report

Attachment G -- Dr. Seeker's comments on the report

Attachment H -- Dr. Lippmann's comments on the report

Attachment I -- The Integrated Human Exposure Committee's draft *Review of the Draft Strategy for
the Analysis of NHEXAS Data"*

Attachment J -- Dr. Mauderly's comments

Attachment K -- The Drinking Water Committee's draft *"Advisory on EPA's Draft Contaminant
Candidate List (CCL) Research Plan"*

Attachment L -- Dr. Morgan's comments

Attachment M -- Dr. Johnson's comments

Attachment N -- Dr. Mauderly's analysis of the issue concerning *"Improving the Science-Policy
Interface"*